

Notice of Allowability	Application No.	Applicant(s)	
	10/031,409	MARUO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 28 October 2005.
2. ☒ The allowed claim(s) is/are 1,4-8,11 and 12.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawing filed 01/18/02 is accepted by the Examiner.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Non-Final Office Action and Applicant's Arguments/Remarks, all filed 10/28/05 is acknowledged.

Claims 1, 4-8, 11 and 12 are pending in this action. Claims 1 and 8 have been amended. Claims 2, 3, 9 and 10 have previously been cancelled. Claims 1, 4-8, 11 and 12 are allowed.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 1, line 3, after the title of the invention, the following has been inserted:
"This application is a 371 of PCT/JP01/04735 filed 06/05/2001. This application claims priority to foreign Japanese Application No. JP 2000-168811 filed 06/06/2000".

Allowable Subject Matter

Claims 1, 4-8, 11 and 12 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Ueda *et al.* - U.S. Pat. No. 5,045,553 & Woo *et al.* - U.S. Pat. No. 6,455,067) does not disclose nor teach or fairly suggest the instantly claimed ointment patch that comprises a support that is composed of a copolymer of vinyl acetate and acrylic acid, wherein the copolymer is obtained by copolymerizing a vinyl acetate, an alkyl ester of a (meth)acrylic acid with the alkyl having 4 to 14 carbon atoms on average, and a (meth)acrylic acid in amounts of 0 to 90 wt%, 10 to 97 wt%, and 0 to 15 wt%, whereby the copolymer is cross-linked. The prior art also fails to disclose or teach a support having 50% modulus of 5 g/cm to 600 g/cm and a water vapor permeability of 100 g/m²/24hrs or higher. In addition, the prior art lacks in the teaching of a patch whereby ointment does not migrate into the support and wherein there is no change in the modulus of the support when the ointment is provided thereon. In contrast, the Ueda *et al.* reference ('553) teaches an ethylene vinyl acetate (EVA) intermediate film, rather than a support as claimed, wherein the EVA film is used to control release of the absorption promoter (Ueda *et al.* column 4, lines 10-17). Ueda *et al.* provide no teaching or even a remote suggestion to use EVA as a support material.

In the response filed 10/28/05, Applicants have further amended the independent claims to 'consisting essentially of' language to exclude the intermediate layers and supports, such as the aluminum support of Ueda *et al.*, that affect the essential characteristics of the invention.

The instant invention demonstrates an improvement over prior art formulations because it provides for a patch and applicator system for administering ointment to the skin, whereby the ointment does not migrate to the support. The patch provides for increased mechanical strength with increased drug-releasing ability and efficacy, due to non-migration of the ointment, as compared to prior art formulations. The patch also does not cause uncomfortable conditions

when applied to the skin of the user. Thus, in view of the deficiencies of the prior art and the improvements demonstrated by the instant invention, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

January 23, 2006



TC-1600

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